elios

BAUSCH + LOMB

Instructions for Use - EN

MLase catalogue number: 512293

1025_IFU_ELIOS laser console_EN_Rev D / 2025-10

CE 0197

MLase REF 513187-00

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1 Introduction

1.1 Manufacturer

MLase is the legal manufacturer of the ELIOS laser console.

1.2 Intended Use and Indication

Intended Use:

The ELIOS system is indicated for use in lowering intraocular pressure (IOP) in the human eye in adults under the guidance of an ophthalmic specialist in professional healthcare facility environment.

The ELIOS system consists of the ELIOS laser console and the ELIOS probe.

The ELIOS laser console is a reusable excimer laser with an expected service life of 10 years.

The ELIOS probe is a sterile single use applicator. The treatment time takes app. 1 minute. The applicator is limited to the use at a single eye.

Indication:

The ELIOS laser console is used only for the treatment of glaucoma.

- Any warranty or guarantee from the manufacturer refers exclusively to the use of the laser in connection with intended use.
- Any use of the operator controls or configuration in any other way than described in this instructions for use can lead to dangerous exposure of radiation.

1.3 General information

The ELIOS laser console is an excimer laser that is used with a custom-built (e.g. ELIOS probe) fiber. The objective, using an ab interno minimally invasive surgical approach, is to ablate portions of the trabecular meshwork and create laser channels to facilitate the outflow of aqueous humor to reduce intraocular pressure.

These instructions for use contain an overview of the safety requirements and the technical data of the device and also a detailed description of the put into service and operation.

These instructions for use must be read, understood and adhered to by the operating personnel. We point out explicitly that we are not accountable for any damage or interruption of operations resulting from nonobservance of these instructions.

- Read instructions for use before using this device.
- Store instructions for use for future look up.

The latest version of the instructions for use can be found on the manufacturer's website (see 6.8.1)

1.4 Side effects and contraindications

Side effects:

- post-operative pressure increase
- intraocular internal bleeding
- lens damage
- postoperative chronic irritation
- pain

Contraindications:

- Patient age below 18
- Patient is suffering from autoimmune disorders (especially collagenosis)

1.5 Scope of delivery

Description	**Amount**
ELIOS laser console	1
Foot switch	1
Power cable 3 m	1
Dummy plug for remote interlock	1
Key for key switch	1
Instructions for use	1

1.6 Medical products approved for use in conjunction with the ELIOS laser console

Compatible medical product:	Description:
ELIOS probe	Model reference: FM270405S or M270405S Manufacturer: WEINERT Fiber Optics GmbH Mittlere-Motsch-Str. 26 96515 Sonneberg Germany
FIDO laser applicator	Model reference: M270405S Manufacturer: WEINERT Fiber Optics GmbH Mittlere-Motsch-Str. 26 96515 Sonneberg Germany
comparable fiber	Specification Fiber: Total length: 2000 mm Hand piece Length: 70 mm Tactile recognition for the identification of the cannula bevel Cannula: Stainless steel cannula of 500 µm diameter. Cannula protrudes 35mm out of the hand piece oblique cut distal 25° Fiber: Ø-core 210 µm Plug: SMA Sterile adapter Length: 44 mm Wavelength: 308 nm Optical properties: Numerical aperture 0.22 General: Sterile product for single use Does not conduct electricity Please note that third-party fibers must have an RFID transponder tag compatible with the ELIOS laser console.

- When using the device, the accompanying documents of the fiber have to be taken into account.

2 Safety

2.1 General Safety notes

2.1.1 Prompts and symbols used

General warning sign

Additional information

2.1.2 Basic safety requirements

Operation of the laser

- The ultraviolet radiation of the ELIOS laser console is invisible.
- The security advice must be adhered to.
- Do not look into the laser beam.
- In accordance with the Medical Device Regulation (2017/745), MLase is obliged to inform you of the following: All serious incidents occurring in connection with the product must be reported to MLase and the competent authority of the Member State in which the user and/or the patient is established.

- Serious incident means any incident that directly or indirectly led to the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. It does not matter whether these have occurred or could occur. The exact definition can be found in Regulation (EU) 2017/745 Article 2 (65). You can find the contact details of the competent authority in your Member State on the internet using the search terms "Competent Authorities for Medical Devices EU".

The ELIOS laser console should only be operated by persons with ophthalmologic specialist or medical / technical training who have been trained by MLase or an authorized service partner.

- The laser is only to be operated by an ophthalmologic specialist.
- Always have spare fibers ready.
- Any use of the operator controls or configuration in any other way than described in this instruction for use can lead to hazards for personnel or patients.
- Changes to the ELIOS laser console are not permitted.
- The ELIOS laser console is not a sterile product.
- During use of the ELIOS laser console at a patient, servicing and maintenance must not be performed.

The ELIOS laser console contains a self-monitoring security mechanism which only recognizes internal electrical or mechanical failures. Erroneous operation is regarded as an external command and will not be recognized as an error.

As for any other electrical devices, the ELIOS laser console has also a certain risk of failure. Therefore, preparation must be made in order to be able to interrupt operation at any time.

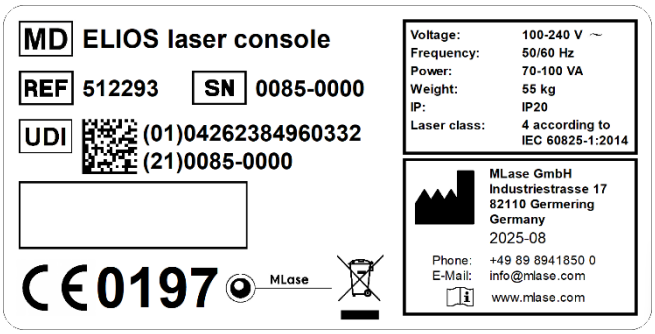
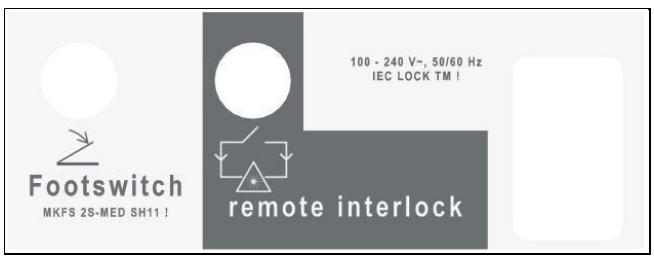
Service and repair work

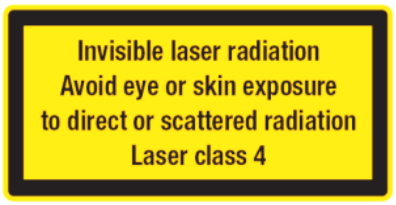
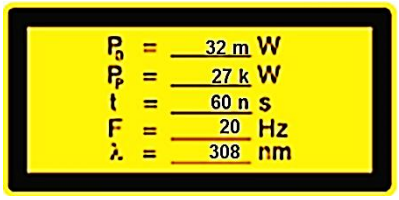
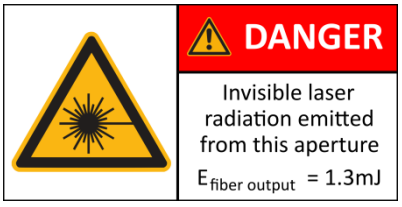
Only personnel from MLase or authorized service partners are allowed to set up, carry out maintenance or repair the ELIOS laser console, failing to do this invalidates any warranty claims. If service work is carried out on the laser which necessitates the opening of the casing of the device, all persons present should wear protective glasses with protection level EN 207:2017 180-315 D LB8 + R LB2 or higher.

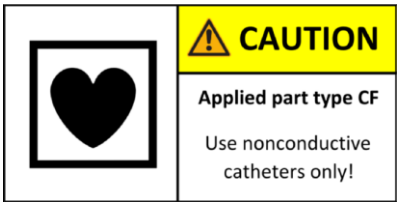
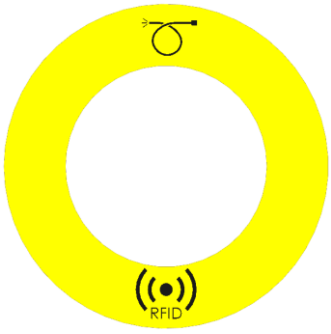
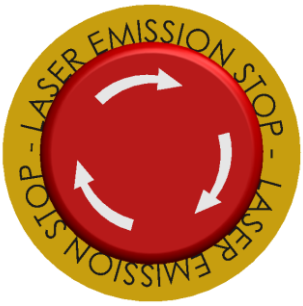
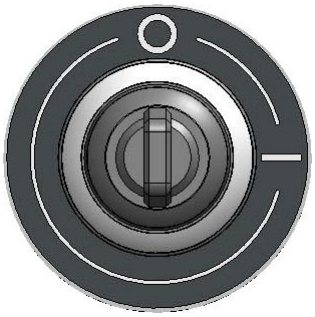
- The casing of the device is only to be opened by service personnel.

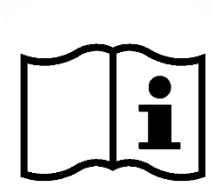
2.2 Labeling of the ELIOS laser console

The ELIOS laser console is marked with an identification plate and warning signs. The following describes the meaning and position of the identification:

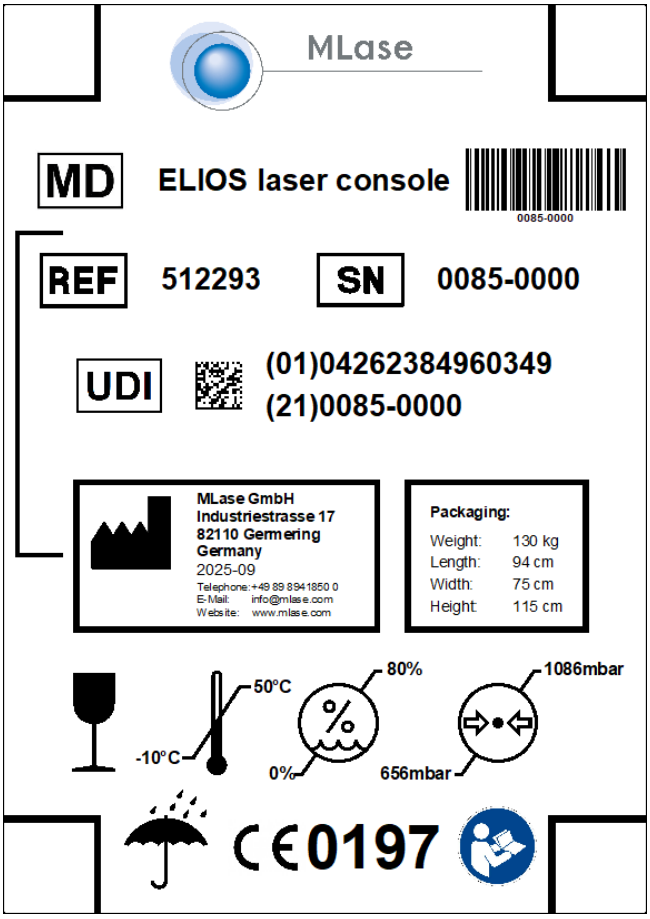
No.	Description of warning signs or label	Figure
1.	The identification plate is located on the backside of the laser (see Fig. 2-1). The symbols used mean: MD Medical device REF Catalogue number SN Serial number UDI Unique Device Identifier Alternating current IP IP protection class Manufacturer and date of manufacture (YYYY-MM) CE 0197 CE marking of conformity with number of Notified Body see 6 electronic instructions for use available	
2.	Labeling of connections. Mains electrical input (“100 – 240 V~, 50/60 Hz IEC LOCK TM !”) foot switch („Footswitch) external Interlock (“remote interlock”)	

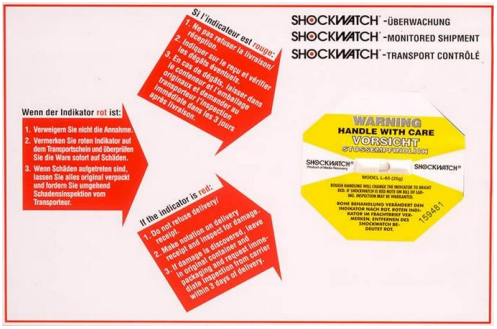
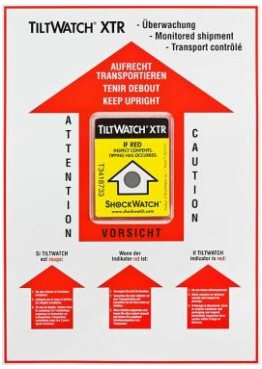
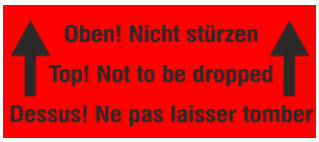
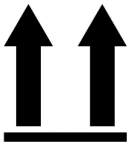
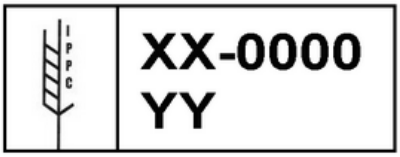
No.	Description of warning signs or label	Figure
	The label is located on the backside of the laser (see Fig. 2-1).	
3.	The ELIOS laser console generates class 4 laser radiation. Neither eye nor skin should be exposed to this invisible radiation. The label is located on the backside of the laser (see Fig. 2-1).	
4.	The laser radiation output information is specified on the pictured label. The label is located on the backside of the laser (see Fig. 2-1).	
5.	Connector for electrical potential equalization. The label is located on the backside of the laser (see Fig. 2-1).	
6.	This symbol indicates that the laser is not to be disposed of in the consumer waste. When the product has reached the end of its functional life, please contact the manufacturer or an authorized service partner. They will then redeem the device and will organize the disposal. This symbol is part of the identification plate (see label 1).	
7.	Follow instructions for use. The label is located on the front side of the laser above the touch panel (see Fig. 2-2).	
8.	The laser warning identification sign warns about the emission of laser radiation at this position. The label is located on the front side of the laser close to the laser beam aperture (see Fig. 2-2).	

No.	Description of warning signs or label	Figure
9.	Defibrillation-proof type CF applied part Only fibers of type CF are allowed to be attached. Only nonconductive catheters may be used. The label can be found under the corresponding connection on the front panel (see Fig. 2-2).	
10.	Connection of the fiber. The label can be found above the corresponding connection on the front panel (see Fig. 2-2). Symbol for radio-frequency identification. Optical fibre applicator	
11.	Identification of the laser emission stop. The label is located on the front side of the laser (see Fig. 2-2).	
12.	Position display for the key switch. O = “OFF” I = “ON” The label is located on the front side of the laser (see Fig. 2-2).	
13.	Energy monitor for the fiber. The label is located on the front side of the laser (see Fig. 2-2).	

No.	Description of warning signs or label	Figure
14.	The symbol “Consult instructions for use” is shown on the start screen of the ELIOS laser console (see Fig. 4-1).	

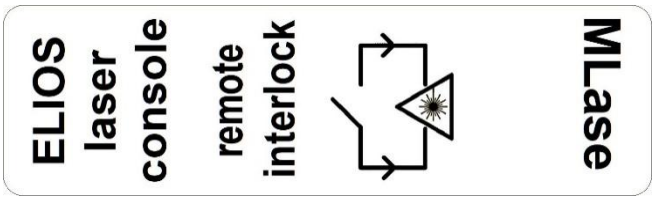
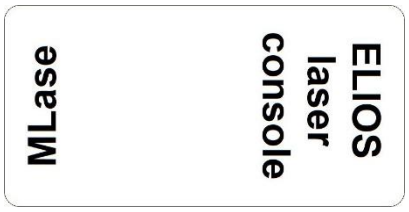
The wooden transport box of the ELIOS laser console is marked with a packaging label. The following describes the meaning and position of the identification:

No.	Description of warning signs or label	Figure
15.	The packaging label is located on the top of the wooden transport box. The symbols used mean:  Fragile, handle with care  Temperature limit  Humidity limitation  Atmospheric pressure limitation  Keep dry	
16.	Two copies of the label “Do not dispose this crate!” are located inside the wooden transport box.	Do not dispose this crate! Please keep for return!

17.	The Label “Shock watch” is also located inside the wooden transport box. The symbols used mean:  No rough handling detected  Potential damage detected	
18.	One copy of the label “Tilt watch” is located on the long and on the short side on the outside of the wooden transport box. The symbols used mean:  No tipping detected  Potential damage detected	
19.	One copy of the label “Hazardous materials class 9” is located on the long and on the short side on the outside of the wooden transport box. The ELIOS laser console is classified in class 9 of dangerous goods.	
20.	One copy of the label “Fragile! Handle with care!” is located on each long side on the outside of the wooden transport box.	
21.	One copy of the label “Top! Not to be dropped!” is located on each long side on the top of the wooden transport box.	
22.	The marking “This side up!” is located on each side on the outside of the wooden transport box.	
23.	The marking “IPPC” is located on each short side on the outside of the wooden transport box.	

	IPPC = International Plant Protection Convention XX = Country code 0000 = Registration number YY = Heat treatments	

The parts used with the ELIOS laser console are marked with labels. The following describes the meaning and position of the identification:

No.	Description of warning signs or label	Figure
24.	The label of the key is located on the key itself. MLase = Manufacturer ELIOS laser console = associated medical device	
25.	The label of the remote interlock is located on the plug itself. The symbol means:  external Interlock (“remote interlock”) MLase = Manufacturer ELIOS laser console = associated medical device	
26.	The label of the power cable is located on the power cable itself. MLase = Manufacturer ELIOS laser console = associated medical device	

27.	The label of the foot switch is located on the foot switch itself. MKFS 2S-MED SH11 = Accessory name SN Serial number of footswitch Date of manufacture (YYYY-MM) IP IP protection classification CSA marking of conformity Manufacturer of footswitch MLase = Manufacturer of associated medical device ELIOS laser console = associated medical device	

- Should the identification plate or warning signs have become detached or unreadable, please contact the manufacturer or an authorized service partner.

Location of the identifications on the ELIOS laser console:

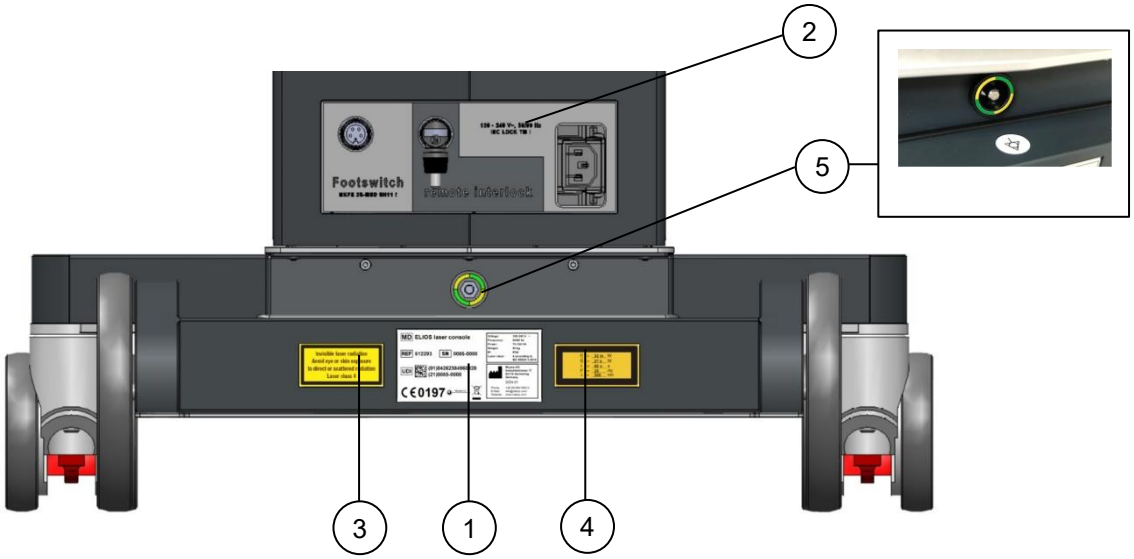


Fig. 2-1: Backside view

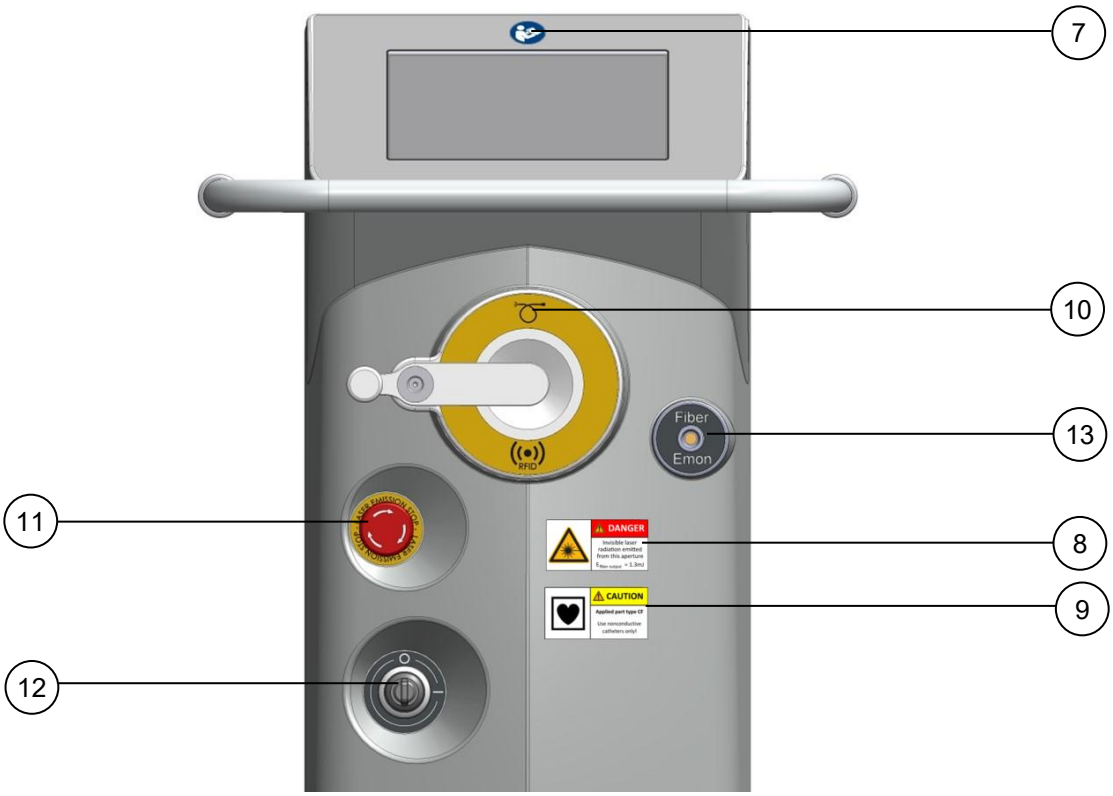


Fig. 2-2: Frontside view

2.3 Safety requirements regarding the site of put into service

The room in which the ELIOS laser console is to be operated must be larger than 6 m³. Sufficient ventilation must be guaranteed. The operating temperature of +18 °C to +30 °C must be met.

- The ELIOS laser console must not be used in areas exposed to explosion hazards or in with oxygen enriched areas.

- There is a risk of fire or explosion when the laser output is used in the presence of combustible materials, solutions or gases or in an oxygen enriched environment. Some materials, e.g. cotton, can, when saturated with oxygen, ignite when exposed to the temperatures that occur during the normal use of the laser appliance. Volatile solvents from glues and flammable solutions used for cleaning and disinfection should be allowed sufficient time to evaporate before the laser apparatus is taken into operation. Attention should also be paid to the fact that bodily gasses can also be flammable. [IEC 60601-2-22:2019]

2.4 Equipment safety against inadvertent laser emission

2.4.1 Foot switch

Laser emission can only be triggered when the foot switch is pressed as far as it will go. The foot switch is provided with a cover. This prevents unintentional triggering of the radiation, e.g. by falling objects or accidental placing of the foot.

2.4.2 Shutter

The path of the laser beam is enclosed internally as well as externally by mechanical shutters. Unregulated laser emission is therefore prevented. The internal shutter is only opened when the foot switch is activated and the shutter is closed as soon as the foot switch is released.

In addition to this the connection of the fiber is also safeguarded by an external shutter. The shutter must be raised by depressing the button in order to be able to connect the fiber.

2.5 Further safety regulations

2.5.1 Essential performance

The essential performance criteria of the ELIOS laser console are energy density at the fiber output, wavelength and pulse duration

To maintain the basic safety of the ELIOS laser console regular service (see 6.3) is mandatory.

To maintain the essential performance criteria energy density at the fiber output regular service of the energy monitor (see 6.4) is mandatory.

To maintain the essential performance criteria wavelength and pulse duration regular exchange of the gas cartridge (laser vessel without circuit) is mandatory (see 6.5).

2.6 Electromagnetic compatibility (EMC)

The ELIOS laser console has been tested regarding EMC and complies with the norm IEC 60601-1-2:2014 + A1:2020.

- Use of the ELIOS laser console adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the ELIOS laser console and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by MLase could result in increased electromagnetic emissions or decreased electromagnetic immunity of the ELIOS laser console and result in improper operation.
- Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the ELIOS laser console, including cables specified by the manufacturer. Otherwise, degradation of the performance of the ELIOS laser console could result.
- The emissions characteristics of the ELIOS laser console make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the ELIOS laser console might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the ELIOS laser console.
- The ELIOS laser console must never be used with the connection cable coiled up. Non-compliance can lead to a reduction in the performance characteristics of the ELIOS laser console.
- The ELIOS laser console must never be used in conjunction with HF surgical devices. Otherwise, degradation of the performance of the ELIOS laser console could result.

2.6.1 Electromagnetic emissions

The ELIOS laser console is designed for use in one of the electromagnetic environments as given below. The customer or operator should ensure that the ELIOS laser console is used in such an environment.

Phenomena	**Compliance**	**Electromagnetic environment**
Conducted and radiated RF emissions	CISPR 11:2015+A1:2016+A2:2019 Group 1	The ELIOS laser console uses HF energy exclusively for its internal functions.
Conducted and radiated RF emissions	CISPR 11:2015+A1:2016+A2:2019 Class A	The ELIOS laser console is designed for use in a Professional healthcare facility environment (e.g. clinics or doctor's offices)
Harmonic current emissions acc. IEC 61000-3-2:2005+A1:2008+A2:2009	Passed	
Voltage changes, voltage fluctuations and flicker acc. IEC 61000-3-3:2013		

2.6.2 Electromagnetic immunity

The ELIOS laser console is designed for use in one of the electromagnetic environments as given below. The customer or operator should ensure that the ELIOS laser console is used in such an environment.

Phenomena	Compliance	Electromagnetic environment
Electrostatic discharge acc. IEC 61000-4-2:2008	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	The ELIOS laser console is designed for use in a Professional healthcare facility environment (e.g. clinics or doctor's offices)
Radiated RF EM fields acc. IEC 61000-4-3: 2006+A1:2007+A2:2010	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment acc. IEC 61000-4-3: 2006+A1:2007+A2:2010	27 V/m at 385 MHz 28 V/m at 450 MHz 9 V/m at 710 / 745 / 780 MHz 28 V/m at 810 / 870 / 930 MHz 28 V/m at 1720 / 1845 / 1970 MHz 28 V/m at 2450 MHz 9 V/m at 5240 / 5500 / 5785 MHz	
Rated power frequency magnetic fields acc. IEC 61000-4-8:2009	30 A/m 50 Hz and 60 Hz	
Proximity magnetic fields acc. IEC 61000-4-39:2017	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	
Electrical fast transients / bursts acc. IEC 61000-4-4:2012	± 1kv, ± 2 kV 100 kHz repetition frequency	
Surges acc. IEC 61000-4-5:2014+A1:2017	± 1 kV Line-to-line ± 2 kV Line-to-ground	
Conducted disturbances induced by RF fields acc. IEC 61000-4-6:2013	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	
Voltage dips acc. IEC 61000-4-11:2004+A1:2017	0 % U_T for ½ cycle at 0,45,90, 135,180,225,270,315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0°	
Voltage interruptions acc. IEC 61000-4-11:2004+A1:2017	0 % U_T for 250/300 cycles	

2.6.3 Compliance with Directive 2014/53/EU

Hereby, MLase declares that the radio equipment type ELIOS laser console is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:
www.mlase.com/Downloads

3 Technical Description

3.1 Structure of the ELIOS laser console

The following figures describe the ELIOS laser console:

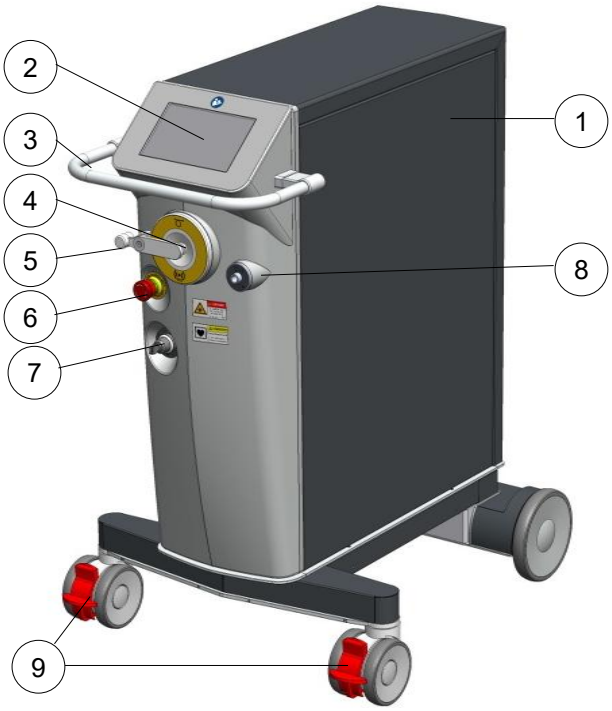


Fig. 3-1: Front side view

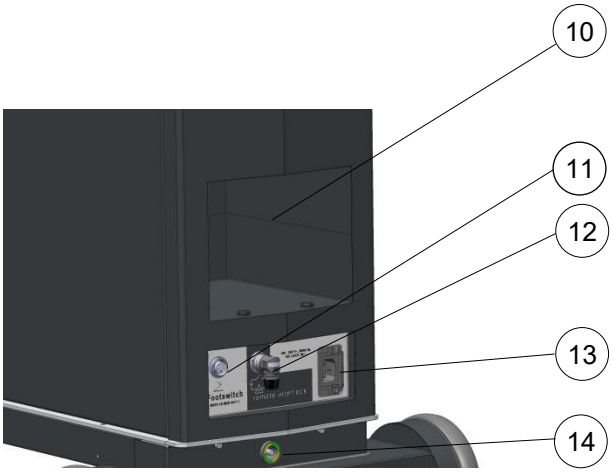


Fig. 3-2: Backside view

1. Basic laser unit
2. Touchscreen
3. Handle with which the device can be lifted, pulled or pushed
4. Coupling unit for the fiber with the connector holder
5. Shutter pushbutton
6. Laser-Emission-Stop
7. Key switch
8. Energy monitor for the fiber
9. Lockable rollers (locking pedal)

10. Compartment for foot switch and power cable
11. Connector for the foot switch
12. Connector for the remote interlock or the dummy plug
13. Connector for the power cable
14. Connector for electrical potential equalization

The following table shows the categorization of parts used with the ELIOS laser console:

Power cable	Detachable part
Interlock plug	Detachable part
Key for the key switch	Detachable part
Foot switch	Accessory

- Circuit diagrams, component lists, descriptions, calibration instructions or other information to assist maintenance personnel are provided on request.

3.2 Operating controls and connections

3.2.1 Main supply

The standard power supply voltage for the ELIOS laser console is 100 – 240 VAC, 50/60 Hz.

- To avoid the risk of electric shocks the ELIOS laser console should only be connected to power supplies with a protective earth conductor.
- The ELIOS laser console should be so positioned that accidental interruption of the power supply during operation is not possible.
- To separate the ELIOS laser console from mains, disconnect the mains plug at the device (Fig. 3-2).
- The ELIOS laser console should be so arranged to enable the removal of the power supply plug on the device at all times (Fig. 3-2).
- In order to remove the power supply cable on the device it is necessary to pull-back the red sliding switch on the connector plug.

- Only power connection cables with locking mechanisms of the type IEC Lock with a length of 3 m and at least 250 VAC/10 A are allowed to be used with the ELIOS laser console.

3.2.2 Foot switch

The foot switch must be plugged onto the connector for the foot switch (see Fig. 3-2). The foot switch is used to trigger the laser emission. Operation of the foot switch activates the laser emission. As soon as the foot switch is released, the laser emission is interrupted.

A cover protects the foot switch from falling objects and unintentional operation.

- Only foot switches identified by the manufacturer are to be used in connection with the ELIOS laser console.

3.2.3 Connector for electrical potential equalization

The ELIOS laser console is equipped with a connector for electrical potential equalization (see Fig. 3-2). The connection to an additional electrical potential equalization can be made by using a potential equalization cable.

The additional electrical potential equalization fulfills the following purposes:

- Avoidance or equalization of differences in electrical potential between electrical device and built-in conducting components in proximity to the patient.
- Dissipation or respectively reduction of increased leakage current.
- Duplication of the protective connector in case of interruption of the earth conductor.

- If an additional electrical potential equalization is available, the connection to the ELIOS laser console is strongly recommended.

3.2.4 Connector for remote interlock

The ELIOS laser console is equipped with a connector for a remote interlock, e.g. a door contact (see Fig. 3-2). If the contacts of the plug connector are open, then the laser emission is interrupted. Further information regarding the connection of a remote interlock to the ELIOS laser console can be obtained from MLase or from an authorized service partner.

- If the case that no remote interlock is being used, the provided dummy plug must be connected to enable operation of the ELIOS laser console.
- If the case that a remote interlock is being used a shielded cable (shield connected to earth potential) must be used.

3.2.5 Key switch

The laser is taken into operation by turning the key switch (see Fig. 3-1) to position “I”.

- When the ELIOS laser console is not in use, the key should be removed from the key switch to prevent any unauthorized operation.
- If the device should be re-activated immediately after being switched off, a pause of at least 5 seconds is necessary.
- The device is designed for continuous operation.

3.2.6 Laser-Emission-Stop

By pressing the red “Laser-Emission-Stop” button (see Fig. 3-1) the laser emission can be immediately interrupted in case of emergency.

To recommence laser operation the red button should be turned clockwise and pulled out simultaneously, so the green ring appears.

- If the device should be re-activated immediately after being switched off, a pause of at least 5 seconds is necessary.

3.2.7 Locking pedal

Both the ELIOS laser console’s front rollers are equipped with locking pedals to prevent movement (see Fig. 3-1). To lock the rollers the pedals should be pressed down. Lifting the pedal or “kicking” against the top of the lock releases the rollers.

- During operation of the ELIOS laser console the locking pedals must be activated.

3.2.8 Connectors for optical fiber and radio equipment

The ELIOS laser console is equipped with two connectors for each end of the optical fiber (see Fig. 3-1). The fiber is connected to the ELIOS laser console as described in Chapter 4.4.3.1. The radio equipment of the ELIOS laser console then scans the RFID tag integrated into the fiber and checks the validity of the fiber. During this process, the ELIOS laser console intentionally emits radio waves at frequencies of 134.2 kHz (± 100 Hz) and at maximum field strength of -5.5 dBµA/m at 10 m for the purpose of radio communication. The radio parameters of the ELIOS laser console have been tested to comply with 2014/53/EU (see Chapter 2.6.3).Once the optical fiber is accepted, the distal end of the fiber can be plugged into the energy monitor for calibration according to Chapter 4.4.3.2 for calibration.

4 Operation of the ELIOS laser console

4.1 Fundamentals

The ELIOS laser console may only be taken into operation when the following requirements are fulfilled:

- The put into service was carried out by an employee of MLase or an authorized service partner.
- The responsible ophthalmic specialist and the operating personnel were given an extensive training by the medical product consultant of MLase or an authorized service partner.

4.2 Preparation

The following points are to be checked before operation of the laser:

- The power cable is correctly inserted into the designated connection (e.g. 230 V/50 Hz).
- The power cable cannot lead to any hindrance and thereby be inadvertently disconnected.
- The power cable is not obviously damaged.
- The locking pedals are activated so that the ELIOS laser console cannot be moved.
- The red “Laser-Emission-Stop” button is extended for use.

4.3 Activation of the ELIOS laser console

The activation of the ELIOS laser console is carried out by turning the key switch to position “I”.

The start screen (Fig. 4-1) is shown with a hint to “Read Instructions before usage!”.

The language of the user interface can be changed by pressing the button on the top right and selecting the desired language.

The main menu is reached by pressing the **“CONTINUE”** button.
You can select the language using the button in the top right corner.

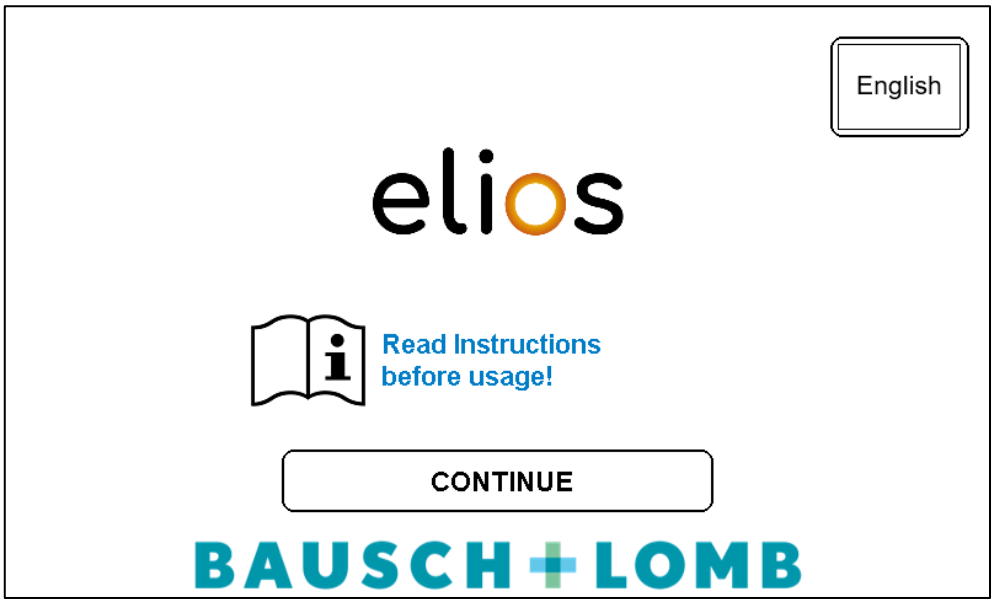


Fig. 4-1: Start screen

4.4 Program sequence

4.4.1 Main menu

The main menu (Fig. 4-2) is divided into the following submenus:

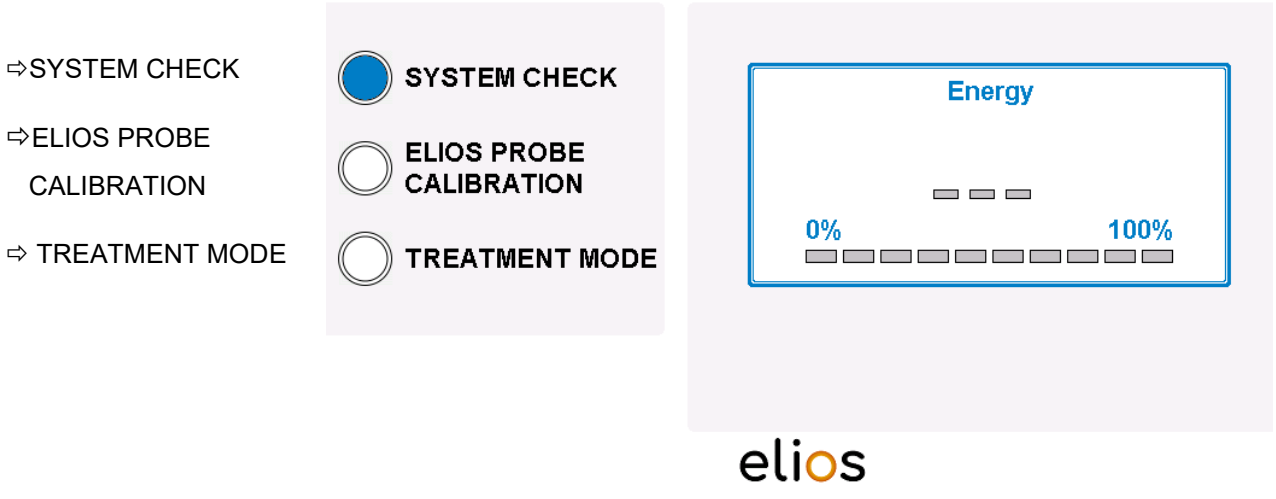


Fig. 4-2: Main menu

4.4.2 SYSTEM CHECK

4.4.2.1 Internal energy control

During the internal energy control the laser energy is set to a preset nominal value. At the same time this is a check if sufficient laser energy is available.

- The prompt to activate the foot switch appears after a delay (after the SYSTEM CHECK) in the header.
- The foot switch must be activated until the power check is completed (as shown by the progress bar) and the energy level of the ELIOS laser console is displayed.
- As soon as the foot switch is released, the button **“CONTINUE”** can be pressed to move on to the ELIOS PROBE CALIBRATION (Fig. 4-3).

- If the foot switch is pressed before “Press footswitch” is shown the internal energy control will not start. The Main menu is then reached again by releasing the foot switch.
- If the foot switch is released before the power check is completed the start screen is shown again. The Main menu is then reached again by pressing **“CONTINUE”.**
- Energy level 31-100 %: Laser ready for use, no actions necessary.
- Energy level 11-30 %: Laser ready for use, contact service as soon as possible.
- Energy level ≤10 %: Laser not ready for use, no treatment possible, service must be contacted.

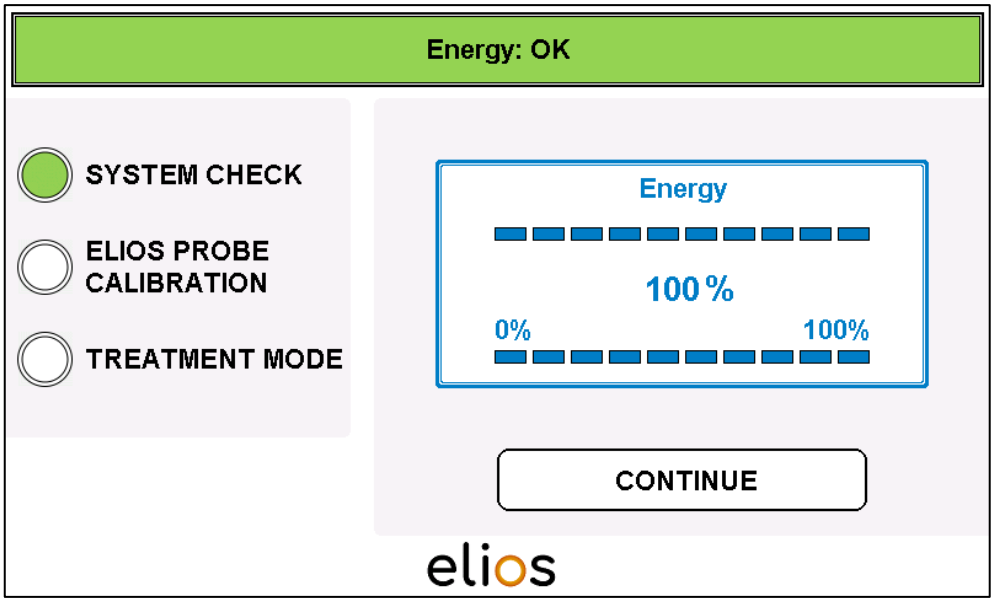


Fig. 4-3: Internal energy control

4.4.3 ELIOS PROBE CALIBRATION

- During the ELIOS PROBE CALIBRATION invisible UV radiation will be transmitted from the fiber. This is indicated by the following laser warning symbol in the control field (Fig. 4-4).

Fig. 4-4: Warning symbol “Caution laser radiation”

4.4.3.1 Connection of the fiber

- The fiber is sterile and must be treated with appropriate care.
- A quartz glass fiber is used as laser transmission system. Tight curves or insufficient fixation can lead to damage of the transmission system and should be avoided. The instructions in the accompanying documents of the fiber must be observed.

The program prompts for the connection of the fiber (ELIOS probe) to the ELIOS laser console to be made (Fig. 4-6).

Raise the shutter by depressing the button and screw the connector of the fiber to the coupling (Fig. 4-5). After that press **“CONTINUE”** (Fig. 4-6).

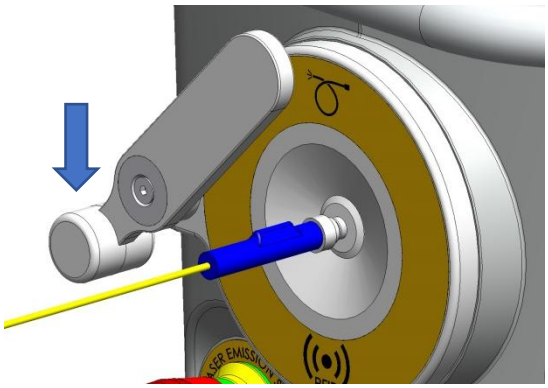


Fig. 4-5: Connection of the fiber (ELIOS probe)

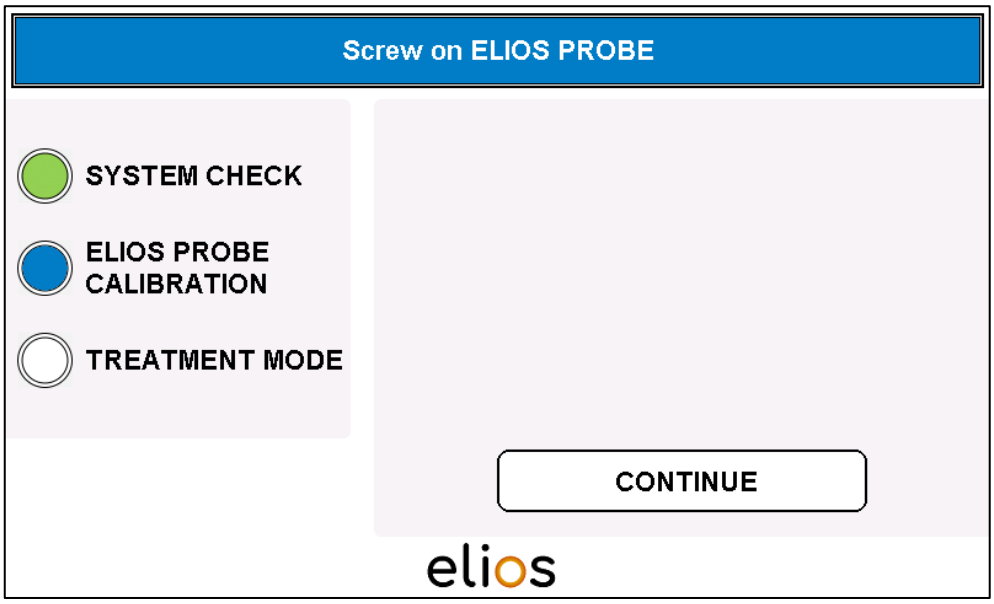


Fig. 4-6: Connection of a new fiber (initial use)

- If a new sterile fiber is connected to the ELIOS laser console, the notification "**ELIOS PROBE: ACCEPTED**" is shown. The next menu item is then available by pressing "**CONTINUE**" (Fig. 4-7).

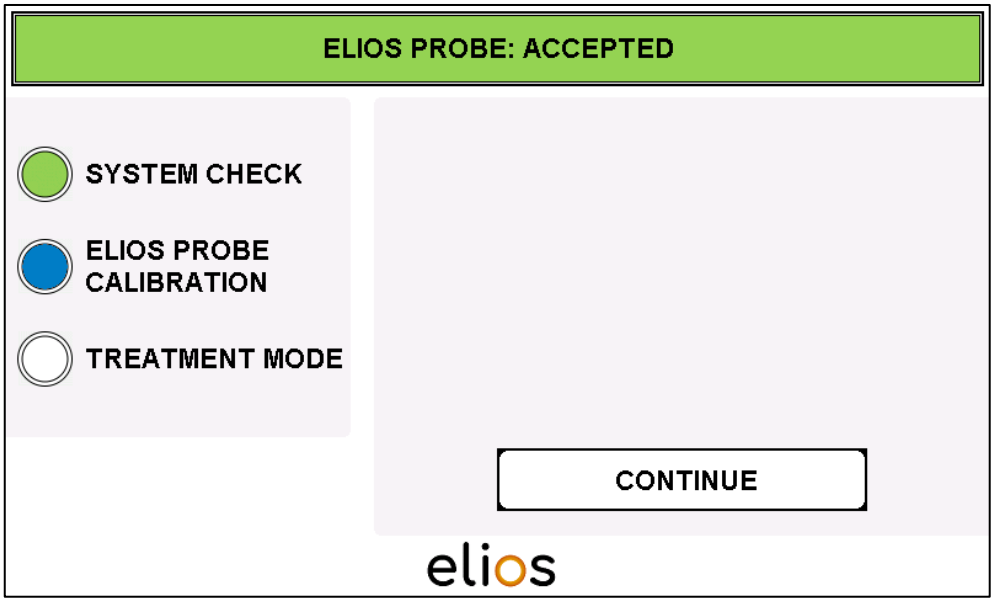


Fig. 4-7: Fiber recognition – ELIOS PROBE: ACCEPTED

- The software recognizes already used and resterilized fibers and prevents their use. The notification "**ELIOS PROBE: REJECTED**" is shown and it is not possible to continue in the program (Fig. 4-8).

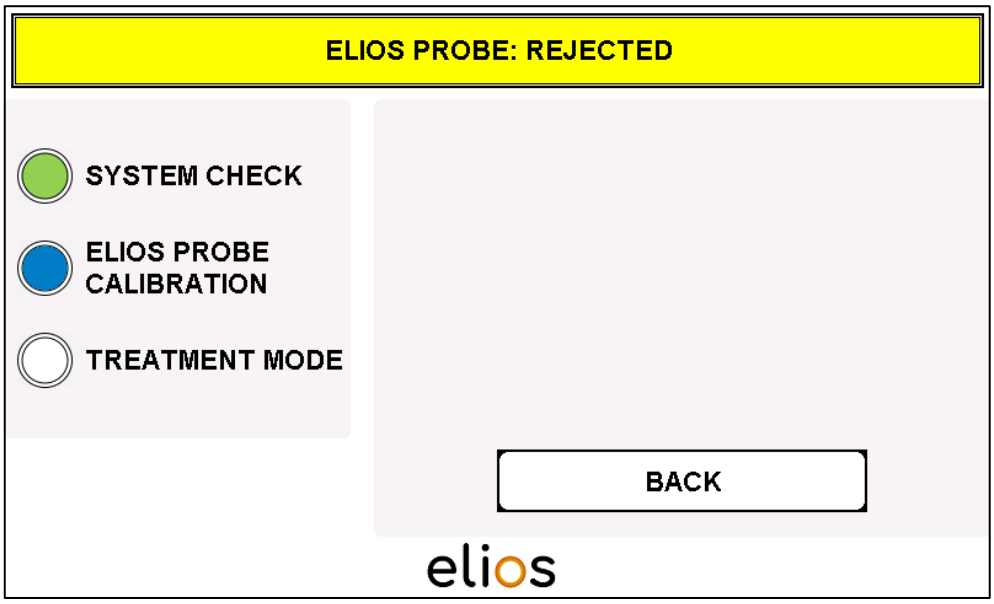


Fig. 4-8: Fiber recognition – ELIOS PROBE: REJECTED

- The fiber must be exchanged for a new one. The program can then be continued as described above. If a new fiber is rejected, please contact MLase or an authorized service partner.
- The previous menu is reached again by pressing "**BACK**" (Fig. 4-8).

4.4.3.2 Fiber calibration

The energy at the distal end of the fiber must be adjusted to 1.3 mJ for treatment. Minimal power fluctuations can be experienced at the fiber output due to transmission disparities conditional of manufacturing of the quartz fibers. At the same time the power measurement constitutes an examination of the laser transmission system for inconspicuous damage.

To avoid any influence on the sterility of the fiber during the energy measurement, the fiber output of the fiber is equipped with a sterile adapter which must be removed after the measurement.

- The fiber with the sterile adapter is to be inserted into the intake of the energy monitor on the front panel of the laser as far as possible (Fig. 4-9).

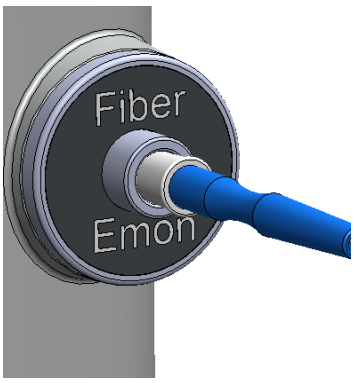


Fig. 4-9: Inserted fiber with sterile adapter

- Tight curves or insufficient fixation can lead to damage of the transmission system and should be avoided.

- The operation is to be confirmed by the “**CONTINUE**” button (Fig. 4-10).

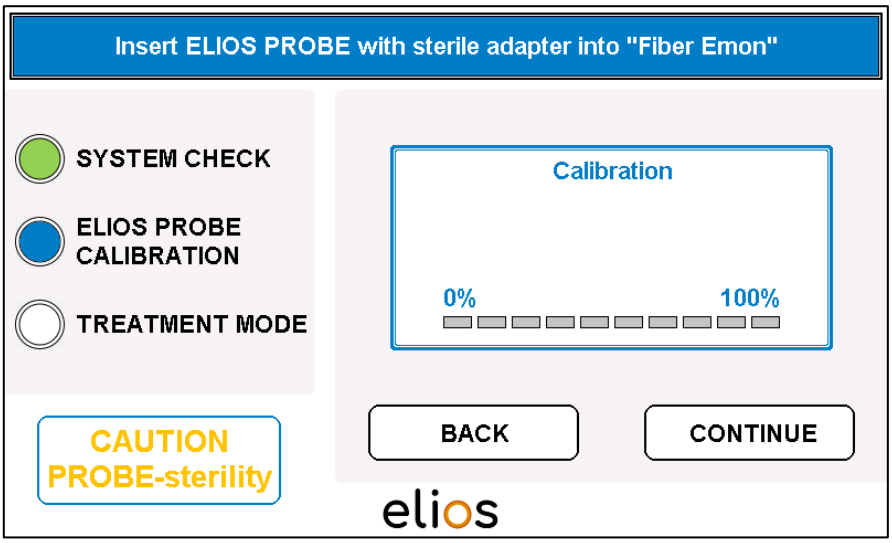


Fig. 4-10: Insert fiber with sterile adapter

The program changes to the energy regulation mode for the fiber.

A progress bar shows the progress of the calibration (Fig. 4-11).

- The foot switch must be activated during the whole energy calibration process.

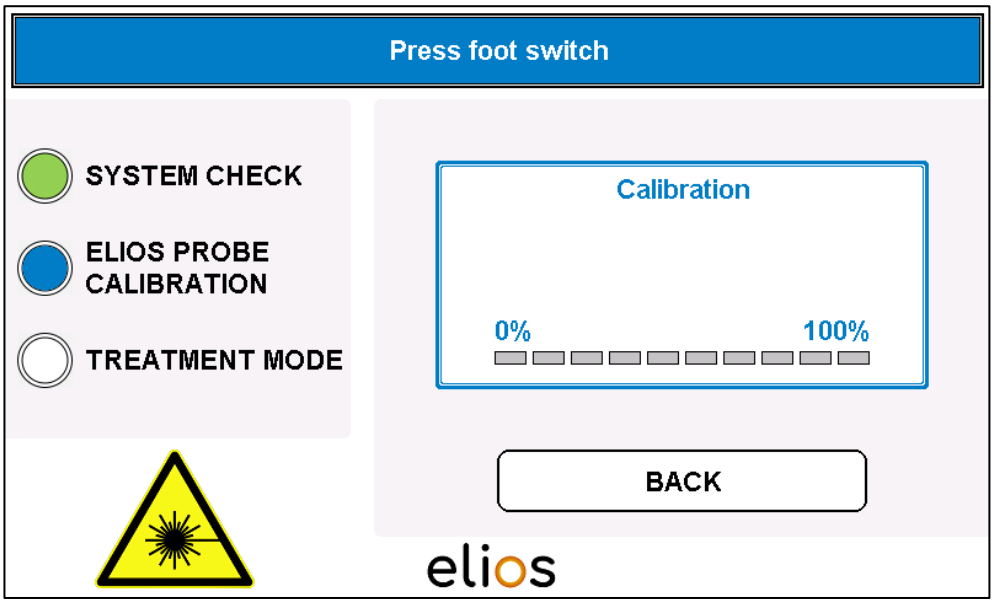


Fig. 4-11: Progress bar during fiber calibration

After successful energy calibration, the following screen is displayed (Fig. 4-12).

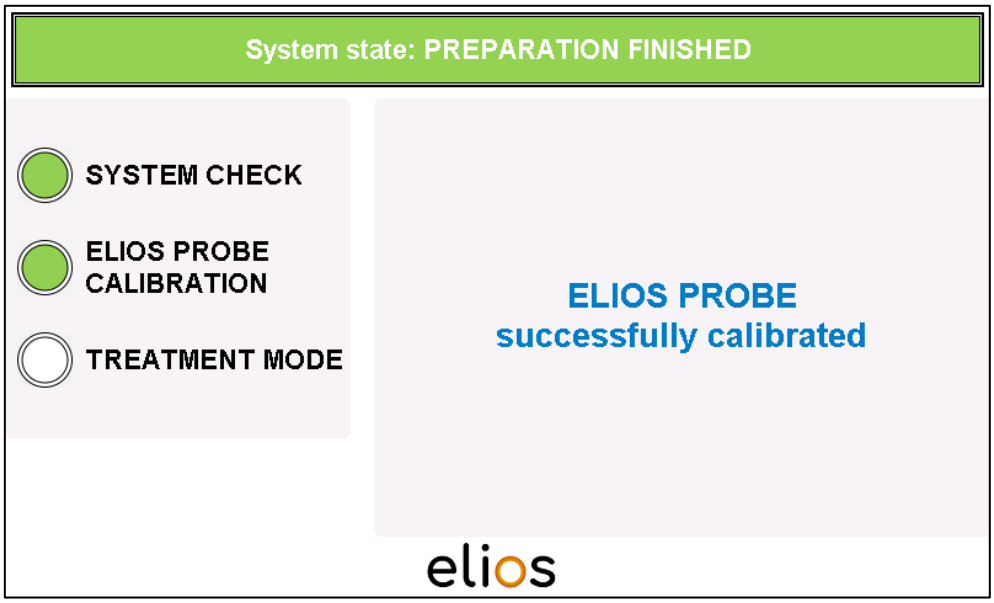


Fig. 4-12: Successful calibration of the fiber

- **Energy calibration and verification of the fiber must be carried out before every treatment.**

- If the necessary energy is not reached at the output of the fiber, the following must be checked:
  → Screw connection of the fiber is tightened **hand tight**?
  → Fiber is inserted into the energy monitor connector **as far as possible**?

  If the output energy is still not reached despite the use of a new fiber, contact MLase or an authorized service partner.

4.4.4 TREATMENT MODE

- During treatment invisible UV radiation will be transmitted from the fiber. This is indicated by the following laser warning symbol in the control field (Fig. 4-13).

Fig. 4-13: Warning symbol “Caution laser radiation”

4.4.4.1 Execution of treatment

In treatment mode the number of remaining microchannels is displayed. The laser is in “ready for TREATMENT MODE“ state.

After the removal of the sterile adapter and the positioning of the fiber in the eye, the “**Start TREATMENT MODE**” button can be activated in the program and the pulse operation mode be started (Fig. 4-14).

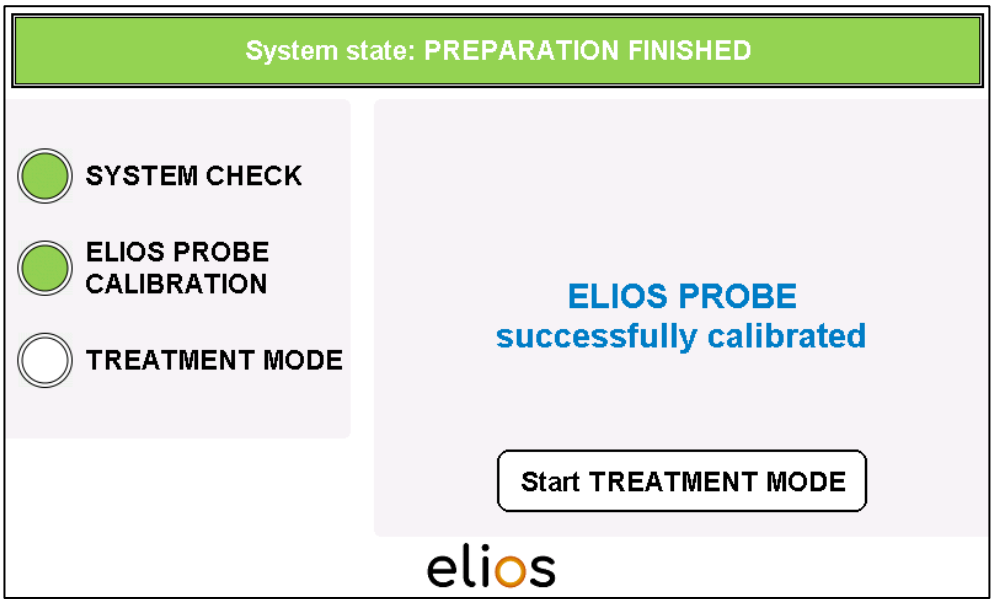


Fig. 4-14: Change to TREATMENT MODE

- The laser is **immediately** triggered by activation of the foot switch, a treatment (20 pulses) can be placed (Fig. 4-15).
- The display shows the remaining number of mircochannels (Fig. 4-15).

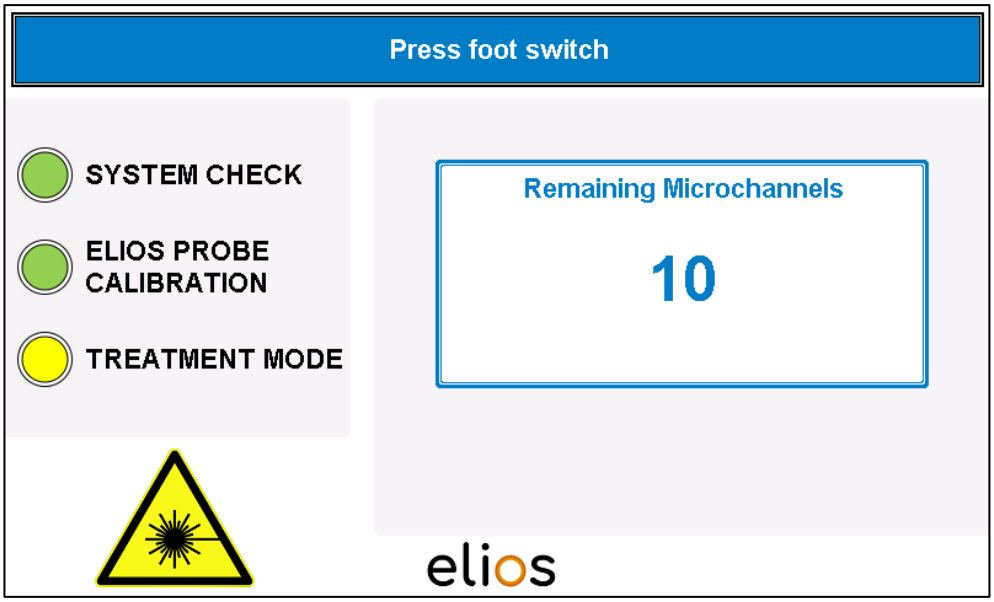


Fig. 4-15: TREATMENT MODE

- **The laser emission is started as soon as the foot switch is activated. The treatment can be interrupted at any time by the foot switch being released.**

- When the maximal number of 20 pulses per microchannel is reached, the laser emission is stopped automatically and the program changes to the next window and a further 20 pulses are available (Fig. 4-16).
- If the foot switch is released prematurely the laser emission is stopped automatically and the program also changes automatically to the next window (Fig. 4-16).

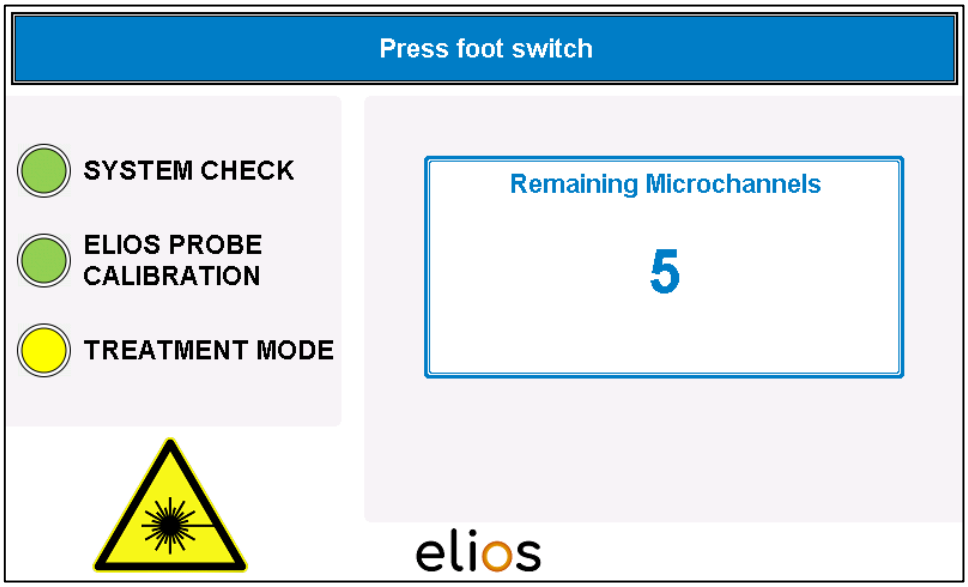


Fig. 4-16: TREATMENT MODE

- This process can be repeated until the maximum number of 10 microchannels to be set is reached.

4.4.4.2 Completion of the treatment

The procedure is completed when the maximal number of 10 possible microchannels is reached.

- After completion of the treatment a summary is shown (Fig. 4-17).

Fig. 4-17: End of treatment

- The ELIOS laser console can now be deactivated by the key switch
- For a new treatment the ELIOS laser console can be restarted by using the key switch
- The user should unscrew the used fiber from the laser
- The fiber should be disposed of in special clinical refuse

5 Technical data

ELIOS laser console	
Catalogue number	512293
Firmware Version Laser	v2.1.0
Firmware Version Display	SKU_1 v3.0
Lasertype	XeCl-Excimer-Laser
Laser class	4
Wavelength	308 nm
Working energy at fiber output	1.3 mJ ± 5 % (Average over 20 Pulses)
Energy density at fiber output	38 mJ/mm^2 ± 5 % (Average over 20 Pulses)
Laser Energy Fluctuations	≤ 3 % Standard deviation
Working power	26 mW
Operational mode	Pulsed
Pulse duration	60 – 120 ns (FWHM)
Pulse repetition frequency	20 Hz
Angle of beam spread at fiber	0.4 rad
NOHD (Nominal Ocular Hazard Distance)	<100 mm
Frequency/Maximum field strength of RFID module	134.2 kHz ± 100 Hz / -5.5 dBµA/m at 10 m
Cooling	Air cooled
Power supply	100 – 240 V~ 70 – 100 VA 50/60 Hz
Electrical protection rating	I
Protective Earth Impedance	≤ 200 mΩ
Dimensions (W x L x H)	58 cm x 74 cm x 87 cm (± 5 cm)
Weight	approx. 55 kg
Operating temperature	+18 °C to +30 °C
Transportation and storage temperature	-10 °C to +50 °C
Maximum altitude (operation) above sea level	3000 m
Atmospheric pressure (operation)	690 mbar – 1070 mbar
Atmospheric pressure (transportation and storage)	656 mbar - 1086 mbar
Relative air humidity (operating, transportation and storage)	80 % non-condensing
IP protection classification of the ELIOS laser console	2 = Protection from access with a finger (< 12.5 mm) 0 = No protection from ingress of water
IP protection classification of the foot switch	X = Protection from solid objects not defined 6 = Protection from powerful water jets
Classification according to Annex VIII of Medical Device Regulation (EU) 2017/745	IIb
CE marking of conformity with number of Notified Body	CE 0197

6 Put into service, maintenance, trouble shooting, disposal

6.1 Put into service, cleaning and disinfection, disposal

6.1.1 Delivery

The ELIOS laser console is usually delivered by a shipping company. The ELIOS laser console is classified in class 9 of dangerous goods. Immediately after delivery please check the condition of the packaging. Check whether the tilt or vibration indicators of the packaging have been triggered. In the event of damage, indicators marked in red or environmental conditions outside the specified limit values, contact MLase or a service partner authorized by MLase for this purpose.

6.1.2 Put into service

The put into service should be carried out by MLase or an authorized service partner otherwise all warranty claims become invalid.

Clean and disinfect the ELIOS laser console according to chapter 6.1.4 before first use.

The ELIOS laser console is ready for treatment as soon as a functional test has been successfully carried out by the service personnel and the ELIOS laser console has been cleaned and disinfected.

6.1.3 Transport

- If it is necessary to move the ELIOS laser console to a different room, care should be taken to eliminate unnecessary vibrations due to thresholds or similar in order to avoid misalignment of the optical components.
- To overcome door thresholds or other barriers the device should be lifted by the handle.

6.1.4 Cleaning and disinfection

The ELIOS laser console must be cleaned and disinfected before the first use and after each use.

Preparation:

Switch off the ELIOS laser console and disconnect the mains plug.

Remove the fiber (ELIOS probe) if there is still one attached to the ELIOS laser console.

Manual cleaning and disinfection:

Wipe the outsides of the ELIOS laser console with a ready-to-use disinfectant for surface disinfection for medical devices. Use only soft cloths for cleaning and disinfection. Carry out the process until no more visible stains can be seen.

The ELIOS laser console may only be wiped with a damp cloth. The ELIOS laser console must not be sprayed. No liquid may get into the opening of the energy monitor or into the plug socket of the fiber.

The ELIOS laser console must not be put back into operation until the cleaning agent and disinfectant have evaporated completely and the surfaces are visibly dry.

For information:

The cleaning and disinfection validation were carried out with the surface disinfectant CaviWipes from Metrex Research. The active ingredients of CaviWipes are alcohol(s) and quaternary ammonium compound(s). The spectrum of activity of CaviWipes is bactericidal and levurocidal.

Follow the instructions for use of the manufacturer of the cleaning and disinfecting agent.

Do not use any chemicals for cleaning and disinfection that are not suitable for the surfaces of the ELIOS laser console, otherwise product damage cannot be ruled out.

Visual inspection:

Check the outsides of the ELIOS laser console after each cleaning and disinfection. In case of damage, contact MLase or a service partner authorised by MLase for this purpose.

Storage:

Store the ELIOS laser console in a dry and dust-free place.

During cleaning and disinfection the following MUST be taken into account:

- The ELIOS laser console must be turned off and power cable must be disconnected before cleaning.
- The operating controls are to be cleaned with a soft cloth.
- The device is not to be sprayed but wiped off with a damp cloth.
- No liquids should be allowed to enter the openings of the energy monitor or the socket for the connection of the fiber
- To allow the complete evaporation of the cleaning agents at the laser should not be taken into use for a considerable time period after the completion of the cleaning.
- The use of more abrasive cleaning agents than those described above may cause damage to the material.

6.1.5 Decommissioning and disposal

The decommissioning and disposal of the ELIOS laser console must be carried out by MLase or an authorized service partner.

6.2 Expected service life

The ELIOS laser console is a reusable excimer laser with an expected lifetime of 10 years. Replace the ELIOS laser console at the following wear criteria:

- Visible damage to the surface, for example corrosion, severe scratching of the touch screen or severe damage to the paintwork.

6.3 Maintenance of the ELIOS laser console

In order to guarantee a failure free operation, the ELIOS laser console must be regularly maintained and calibrated. MLase stipulates that routine maintenance must be carried out on the ELIOS laser console every 12 months. The ELIOS laser console does not contain any components that can be maintained by the operator. Safety tests such as electrical safety checks may also be carried out by a medical technician under observance of all the relevant technical directives.

- Maintenance work on the ELIOS laser console should only be carried out by MLase or by a service partner authorized by MLase.

- The ELIOS laser console must not be modified or altered.
- During maintenance, the safety instructions in chapter 2 must be followed to avoid exposure to hazardous laser radiation.

6.4 Maintenance of the energy monitor

Adjustment of the external energy monitors for measurement of the power of the fiber must be carried out at least once a year.

- The adjustment is only allowed to be carried out by MLase or an authorized service partner.

6.5 Regular exchange of gas cartridge

The laser gas inside the laser tube of the ELIOS laser console degrades while using the laser as well as not using the laser. The operating life of the gas for the ELIOS laser console is guaranteed for 6 months. The gas status test is carried out during the activation of the laser. If the energy level is only 11-30% a warning notification “Energy: LOW” shows up. The ELIOS laser console can be used but we recommend contacting MLase or authorized service partners to arrange a maintenance appointment **as soon as possible**. If the energy level goes to 10% or lower, laser operation is no longer possible and an exchange of the gas cartridge (Laser vessel without circuits) is compulsory. The exchange must be carried out by a trained service partner.

- Gas cartridge exchanges are only allowed to be carried out by MLase or an authorized service partner.

6.6 [Chapter omitted]

6.7 Error messages and warnings

6.7.1 Warnings

If the energy level during SYSTEM CHECK is only 11-30% a warning notification “**Energy: LOW**” shows up (Fig. 6-1). The ELIOS laser console can be used but we recommend contacting MLase or authorized service partners to arrange a maintenance appointment **as soon as possible**.

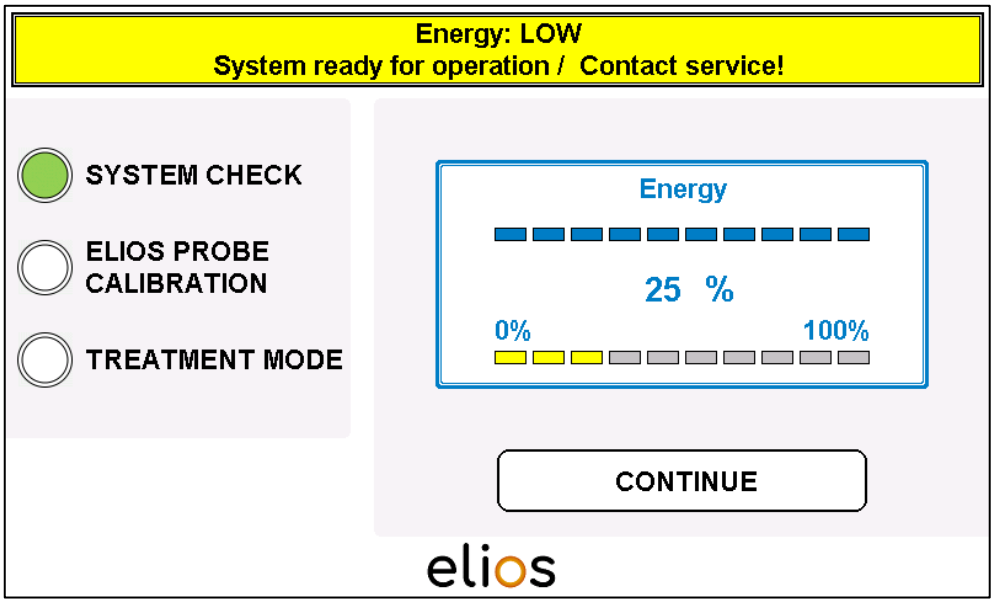


Fig. 6-1: Warning “Energy: LOW“

6.7.2 Error messages

The software recognizes already used and resterilized fibers and prevents their use. The notification “**ELIOS PROBE: REJECTED**” (Fig. 6-2) is shown in the header and it is not possible to continue in the program. This notification also occurs if no fiber is detected. It is not possible to continue in the program. Push “BACK” and exchange the fiber for a new one.

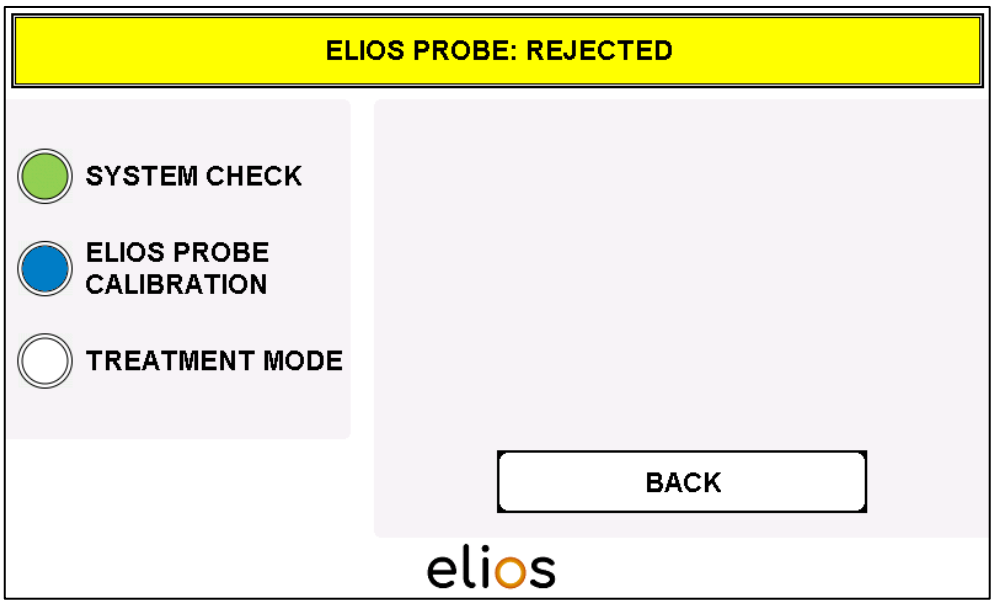


Fig. 6-2: Error “ELIOS PROBE: REJECTED”

A SYSTEM ERROR always leads to program interrupt. It is not possible to continue in the program. A restart of the program is only possible by switching the ELIOS laser console off and on again.

SYSTEM ERRRORs are indicated by a yellow pop-up window with the structure as shown below (Example: Fig. 6-3).

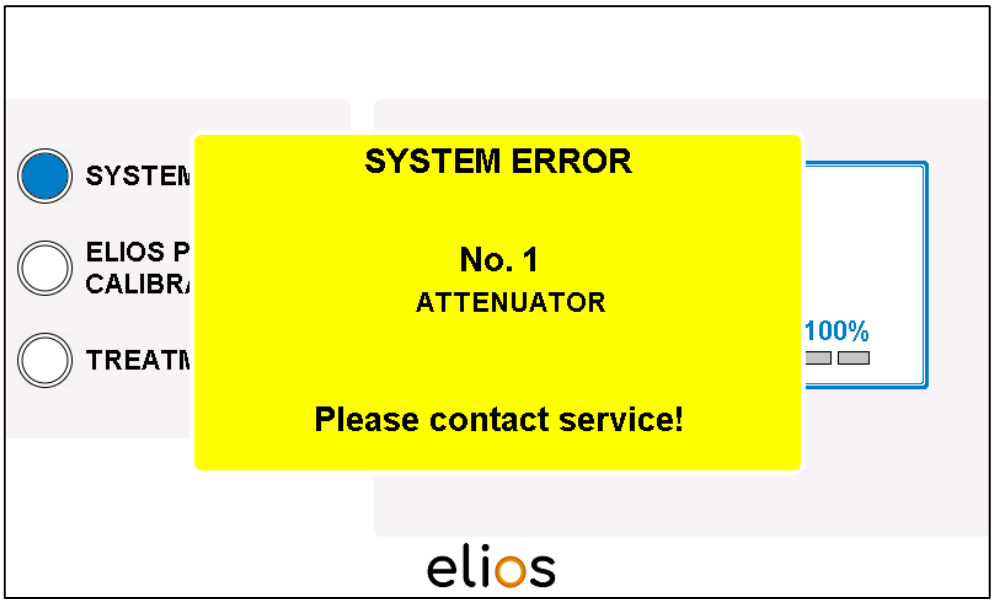


Fig. 6-3: SYSTEM ERROR

The type of failure as well as the number is explained in the table below:

No.	Error message:	Explanation:	Actions:
1	ATTENUATOR	No feedback from attenuator	⇨ contact MLase / service partner.
2	SHUTTER	No feedback from shutter	⇨ contact MLase / service partner.
3	ENERGY	Energy level during SYSTEM CHECK (see 4.4.2.1) is 10% or lower.	⇨ contact MLase / service partner.
4	ENERGY	Target value of internal energy control not matched	⇨ contact MLase / service partner.
5	ENERGY	The transmission of the laser transmission system (quartz fiber) is too low or the sterile adapter is not inserted into the intake of the energy monitor of the laser as far as possible.	⇨ Check whether the fiber with sterile adapter is inserted into the intake of the energy monitor of the laser as far as possible. Use another fiber. On repeated occurrence contact MLase / service partner.
6	ENERGY	The energy necessary of 1.3 mJ (± 5%) at the fiber tip is not reached.	⇨ contact MLase / service partner.
7	ENERGY	The energy necessary of 1.3 mJ (± 5%) at the fiber tip is exceeded by more than 70% during treatment.	⇨ contact MLase / service partner.
8	ELIOS PROBE	Between the confirmation that a valid fiber is attached and the treatment start, the fiber is recognized as invalid or not at all.	⇨ Switch the ELIOS laser console off and on again. On repeated occurrence contact MLase / service partner.
9	ENERGY	Laser energy fluctuates too much.	⇨ Switch the ELIOS laser console off and on again. On repeated occurrence contact MLase / service partner.

6.8 Manufacturer, service

6.8.1 Manufacturer

MLase GmbH	phone	+49-(0)89-693 377-0
Industriestrasse 17	FAX	+49-(0)89-693 377-10
82110 Germering	email	Feedback_EXTRA@mlase.com for feedbacks and complaints
GERMANY		Service_EXTRA@mlase.com for service and maintenance issues
	website	www.mlase.com

In order to guarantee a failure free operation, the ELIOS laser console must be regularly maintained and calibrated. MLase stipulates that routine maintenance must be carried out on the ELIOS laser console every 12 months. The ELIOS laser console requires the regular exchange of the gas cartridge. The exchange should only be carried out by MLase or an authorized service partner. Please contact service! In the case of problems and questions please consult our medicinal product consultant.

Our medicinal product consultant carries out training in the operation of the ELIOS laser console as well.

In the case of questions and problems please quote the serial number of the ELIOS laser console in order to avoid delays in the execution of the service.

The serial number can be found on the identification plate close to the sign “SN” (see Chapter 2.2 No. 1 and Fig. 2-1) at the backside of the ELIOS laser console.